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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/606,969

06/25/2003

Guohua Chen

ARC 3135 R1

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23377

7590

11/15/2006

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EXAMINER

SILVERMAN, ERIC E

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/606,969	<b>Applicant(s)</b> CHEN ET AL.	
	<b>Examiner</b> Eric E. Silverman, PhD	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply, and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2006.
- 2a) ☒ This action is **FINAL**.      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-60 and 105 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-60 and 105 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicants' response and amendment filed 10/13/2006 have been received.

Pursuant to amendment, claims 1 – 60 and 105 are pending.

#### ***Double Patenting***

Claim 105 **remains** provisionally rejected under 35 U.S.C. 101 for claiming the same invention as that of claim 79 of copending Application No. 10/701,939.

Claims 1 – 10, 14 – 20, 27 – 30, 35 – 46, 50, 53, 57 – 60 **remain** provisionally rejected under the nonstatutory judicially created doctrine of obviousness type double patenting as unpatentable over claims 1, 2, 7 – 9, 15, 18 – 20, 26, 27, 32 – 34, 40, 43 – 45, 49, 50, 54, 46, 57, 63, 66 – 68 of copending Application No. 10/701,939.

Claims 1 – 9, 15 – 17, 24 – 26 **remain** provisionally rejected under the nonstatutory judicially created doctrine of obviousness type double patenting as unpatentable over claims 1, 2, 4, 6, 8, 12, 13, 14, 17 – 20, 22 of copending Application No. 10/857,609.

#### ***Response to Arguments***

Applicants' request that the statutory rejection be held in abeyance, as per MPEP 804.B.2. Applicants' also note that the nonstatutory rejections may be overcome by amendment or terminal disclaimer at a later stage in the prosecution. Nonetheless since other issues relating to patentability are yet unresolved, these rejections must be **maintained**.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 – 60 and 105 **remain** rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record and those discussed below.

### ***Response to Arguments***

Applicants' arguments have been fully considered, but are not persuasive.

With regard to the term "low molecular weight", the "definition" of this term provided in the specification is itself indefinite because of the use of the term "preferably". It is not clear if the actual definition encompasses only the broadest embodiment, or if the term is limited to one of the "preferred" embodiments.

With regard to the term "miscibility in water of less than 7%", this issue is resolved by Applicants' arguments. However, the claims containing this term are still rejected under this statute for containing other indefinite phrases, or for ultimately depending on claims that contain such phrases without rectifying the issues relating thereto.

With regard to the term "amount effective to plasticize", Applicants' argue that the term "amount effective" is defined by its function. However, plasticizing a polymer is a term of degree. To plasticize means to make a polymer softer or more flexible by addition of an agent. It is not clear how much the polymer must be "plasticized" in order for the amount to be "effective".

With regard to the term "lower alkylene", the "definition" of this term provided in the specification is itself indefinite because of the use of the term "preferably". It is not clear if the actual definition encompasses only the broadest embodiment, or if the term is limited to one of the "preferred" embodiments.

With regard to independent claims 7-9 and 44-46 not further limiting parent claims 2 and 29, this issue is resolved by Applicants' remarks. However, these claims remain rejected for ultimately depending on an indefinite claim without rectifying the issues relating thereto.

With regard to the phrase "lactic acid based polymer" the portions of the specification cited in Applicants' reply do not provide a definition of this term. Paragraphs 80-81 merely provide a few, non-limiting examples and preferred, non-limiting, molecular weights. Thus, the term is not defined in the specification, and its metes and bounds are not clear to the artisan.

With regard to the phrase "analogous, derivatives, and fragments thereof", even though these terms may be used in the specification or the art, there is nothing to guide the artisan as to what these terms encompass. Since it would not be completely clear in every case whether or not a particular substance is an "analogous, derivatives, and fragments thereof", the metes and bounds of the claim are not defined, and claims containing this phrase are properly rejected.

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 – 24, 27 – 32, 34 – 47, 49 – 54, 57 – 60 and 105 **remain** rejected under 35 U.S.C. 102(a) and 35 U.S.C. 102(e) as being anticipated by WO 02/38185 for reasons of record and those discussed below.

***Response to Arguments***

Applicants' arguments have been fully considered, but are not persuasive.

Applicants' argue that the '185 reference does not teach a solvent having a miscibility of less than 7% in water. In response, it is noted that the reference teaches the use of benzyl alcohol and benzyl benzoate (claim 7), which are understood to have this property. It is noted that benzyl alcohol is recited as an acceptable solvent in claim 45 of instant application, and benzyl benzoate is recited as an acceptable solvent in claim 46 of instant application.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 33 **remains** rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/38185.

***Response to Arguments***

Applicants' arguments have been fully considered, but are not persuasive. Applicants' argue that the '185 reference does not teach a solvent having a miscibility of less than 7% in water. In response, it is noted that the reference teaches the use of benzyl alcohol and benzyl benzoate (claim 7), which are understood to have this property. It is noted that benzyl alcohol is recited as an acceptable solvent in claim 45

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of instant application, and benzyl benzoate is recited as an acceptable solvent in claim 46 of instant application.

Claims 25, 26, 48, 55, and 56 **remain** as being unpatentable over WO 02/38185 in view of WO 00/74650.

### ***Response to Arguments***

While Applicants' did not directly address this rejection, it is understood that Applicants' intended the remarks relating to "the obviousness rejections based on WO 02/28185 to apply to this rejection as well. To the extent that this understanding is correct, these arguments are not persuasive for the same reasons outlined above.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

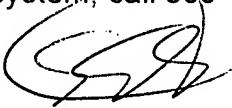
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571 272 8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Eric E. Silverman, PhD  
Art Unit 1615



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